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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,997	06/27/2003	Darwin J. Prockop	57616-5016CT1	8493

23973 7590 05/15/2007

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EXAMINER
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KELLY, ROBERT M

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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05/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,997	<b>Applicant(s)</b> PROCKOP ET AL.	
	<b>Examiner</b> Robert M. Kelly	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendments and arguments of 2/27/07 are entered.

Claims 1, 7, and 17 are amended.

Claims 9-15 are cancelled.

Claims 1-7 and 17-18 are pending.

### ***Election/Restrictions***

Applicant's cancellation of Claims 9-15, previously drawn to non-elected subject matter, obviates all objections and/or objections to such claims, and therefore, such objections and/or rejections are withdrawn.

Hence, Claims 1-7 and 17-18 are presently considered.

### ***Claim Objections***

In light of the amendments to Claim 17, the objection to such claim is withdrawn.

Specifically, the predifferentiation step has been removed from Claim 17.

### ***Drawings***

In light of the amendments, the objection to the drawings is now withdrawn. To wit, original Figure 7 is now also present as Figure 6.

***Specification***

In light of the amendment, the previous objection to the specification is withdrawn.

To wit, the figures are now again consecutively numbered with addition of a figure 6.

However, the specification is now objected to for not containing a brief description of such figure in the drawings. To wit, Applicant has previously cancelled Figure 6 and all references thereto in the specification (Response of 9/16/06). The presently presented amendment now adds back a Figure 6, using another copy of original Figure 7, and Further rennumbers the reference to Figure 7 to make it refer to Figure 6 in the brief description of the drawings. However, at present there is no brief description of drawings which describe Figure 7.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In light of the amendments, the rejections of Claims 1-7 and 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn.

Claims 1-7 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons necessitated by amendment.

Claim 1 recites the limitation "astrocyte". There is insufficient antecedent basis for this limitation in the claim.

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Claim 17 recites the limitation "said cells are cultured in vitro" in Claim 1. There is insufficient antecedent basis for this limitation in the claim. To wit, the term "said cells" can refer to either the "pre-differentiated isolated stromal cells [the astrocytes which are formed from differentiating the stromal cells]" or "isolated stromal cells". Hence, it is unclear which cells are being cultured. Such is further confused with the "co-culturing" as "co-culturing" is a subset of "culturing" and as such, when amending the claims, Applicant should keep in mind that these claims may be objected to for claiming the same thing if amended incorrectly.

Claims 27 and 17-18 are rejected for depending from a rejected base claim and not overcoming the lack of clarity in such base claim.

***Claim Rejections - 35 USC § 112 – new matter***

In light of the amendments, the rejections of Claims 1-7 and 17-18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are withdrawn.

Specifically, the claims now embrace only pre-differentiation by co-culturing the cells in vitro, excluding the non-possessioned embodiments of in vivo differentiation.

***Claim Rejections - 35 USC § 112 – new matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments, the rejections of Claims 1-7 and 17-18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are withdrawn.

Specifically, the claims no longer specifically embrace a second differentiation in vivo.

Still further, it should be noted that Applicant has demonstrated support for co-culturing of isolated stromal cells with astrocytes to produce cells with the phenotypic characteristics of astrocytes, as p. 6, lines 24-28 demonstrate that the isolated stromal cells may be co-cultured with any specific differentiated cell type, to produce cells with the characteristics of the differentiated cell, and p. 27, lines 5-7 demonstrate that such co-culturing may be performed to make astrocytes, and is further supported by pp. 15-16, paragraph bridging, which demonstrates that such support is based on a finding that human stromal cells carry a marker for early astrocyte development after co-culturing with rat astrocytes (Applicant's argument of 2/27/07, p. 9).

***Claim Rejections - 35 USC § 112 - Enablement***

Claims 1-7 and 17-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

***Response to Argument - Enablement***

Applicant's arguments of 2/27/07 have been fully considered but are not found persuasive.

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Applicant broadly argues that given the description in the specification and examples provided, the claims are enabled (p. 10, last paragraph).

Such is not persuasive. The Examiner has considered Applicant's description and examples, and still finds the claims are not enabled, as is of record in the analysis provided. Broad argument does not supplant the need to point out with particularity where the Examiner's reviewed data and/or analysis are incorrect.

Applicant argues case law to demonstrate that the claims do not lack utility (p. 11, paragraph 1).

Such is not persuasive. Applicant does not face a rejection under 35 USC 101 for lacking utility, but a rejection under 35 USC 112, first paragraph, for lacking enablement.

Applicant argues that the optimizing of dosages is routine and therefore, the claims are enabled (pp. 11-12, paragraph bridging).

Such is not persuasive. The Examiner has provided many reasons for a lack of enablement, which are compounded by optimizing dosages, and as such the claims remain non-enabled, as it would amount to inventing the claimed invention for Applicant. For example, these claims, although only requiring administration of the cells to the human brain of an individual suffering from a disease/disorder/condition of the CNS, are only interpreted to treatment (e.g., Official Action of 6/3/05, p. 8, last paragraph). Moreover, it is clear that it is not reasonably predictable for any particular treatment (Id., pp. 6-20).

Hence, these claims remain rejected as not being enabled for any particular therapy and in humans.

***Conclusion***

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

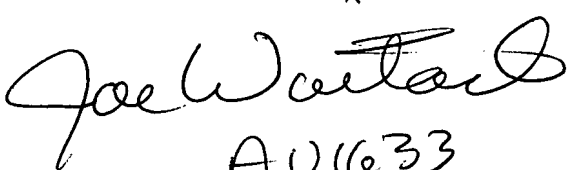
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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